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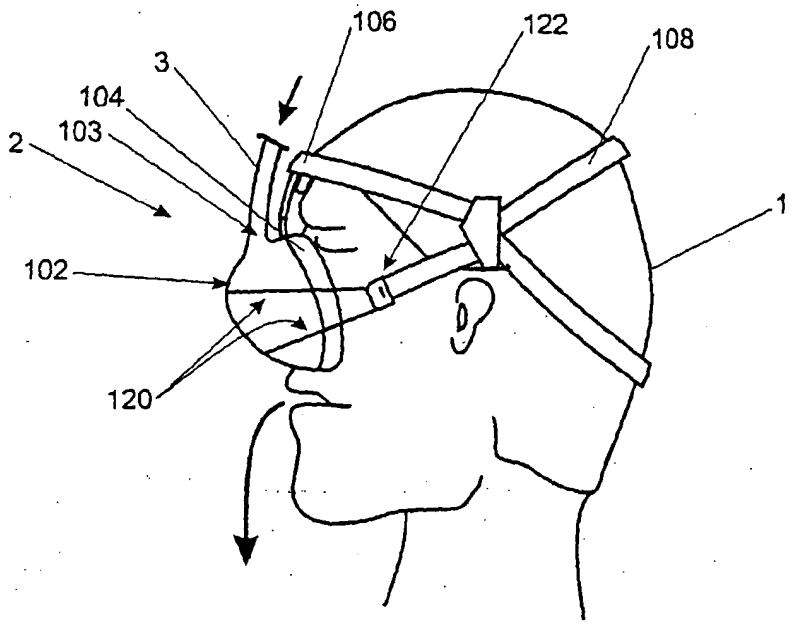

(57) Abstract: A CPAP system for supplying humidified gases to a user. Various interfaces are described for delivering the gases. A mask cushion including a deformable cushion and thin sheath is described. A forehead rest with a horizontal pivot is attached to the mask. An outlet vent to reduce the noise from exhausted carbon dioxide is described. A mouthpiece is also described with an outlet diffuser including Heat Moisture Exchanger Material.

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BREATHING ASSISTANCE APPARATUS

FIELD OF INVENTION

This invention relates to patient interfaces particularly though not solely for use in delivering CPAP therapy to patients suffering from obstructive sleep apnoea (OSA).

BACKGROUND OF THE INVENTION

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the user. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

One requisite of such respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 5,243,971 and US Patent No. 6,112,746 are examples of prior art attempts to improve the mask system US Patent No. 5,570,689 and PCT publication No. WO 00/78384 are examples of attempts to improve the forehead rest.

Where such masks are used in respiratory therapy, in particular treatment of obstructive sleep apnea (OSA) using continuance positive airway pressure (CPAP) therapy, there is generally provided in the art a vent for washout of the bias flow or expired gases to the atmosphere. Such a vent may be provided for example, as part of the mask, or in the case of some respirators where a further conduit carries the expiratory gases, at the respirator. A further requisite of such masks is the washout of gas from the mask to ensure that carbon dioxide build up does not occur over the range of flow rates.

In the typical flow rates in CPAP treatment, usually between 4cm H_2O to 20cm H_2O, prior art attempts at such vents have resulted in excessive noise causing irritation to the user and any bed partners.

Various approaches have been developed in the prior art to attempt to reduce the noise when CPAP therapy is provided. For example, in PCT Patent Application No. WO98/34665 it has been proposed that the vent include a resilient plug with rounded edge apertures to reproduce noise. However, this is not entirely effective in eliminating the extra noise created by a vent at the mask.

In common with all attempts to improve the fit, sealing and user comfort is the need to avoid a concentrated flow of air at any portion of the respiratory tracts. In particular with oral masks or mouthpieces it is a disadvantage of prior art devices that the oral cavity may become overly dehydrated by use of the device, causing irritation and possible later complications.

SUMMARY OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface which goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in one aspect the invention may broadly be said to consist in a device for delivering a supply of gases to a user comprising:

a patient interface, in use in fluid communication with said supply of gases, engaging with said user and thereby supplying said gases to said user.

outlet means associated with said patient interface including a plurality of outlet vents formed in a flexible portion of said outlet means, said outlet means in use passing a substantial portion of the expired gases of said user.

Preferably said patient interface is a mouthpiece.

Alternatively said patient interface is a nasal mask.

Preferably said mouthpiece comprises:

a vestibular shield having an inner surface and an outer surface, said vestibular shield having a predetermined height which will overlap said user's teeth and gums

when positioned in the mouth vestibule of said user;

gases passageway means extending from said outer surface of said vestibular shield to said inner surface of said vestibular shield for allowing the passage of said gases through said mouthpiece; and

extra-oral sealing means associated with said gases passageway which may be adjusted into one of two configurations, a first condition when said mouthpiece is inserted into said user's mouth being substantially unengaged with said user's face, and a second condition when correctly positioned in said user's mouth being substantially engaged with said user's face and under compression thereupon.

Preferably said nasal mask comprises restraining means attached to or around the head of said user, a hard body portion having an inlet receiving said supply of gases and an open section, sealing means attached to said body portion substantially contoured to the facial contours of said user and a receiving means attached to said hard body which in use engages with said restraining means.

Preferably said flexible portion of said outlet means comprises a sleeve having a plurality of outlet vents, said sleeve attaching over said outlet means, said sleeve composed of a substantially flexible material, said outlet means having a outlet aperture and in use said sleeve located on said outlet means such that said outlet aperture matches up with said plurality of outlet vents thereby in use passing a substantial portion of the expired gases of said user.

Alternatively, said outlet means is either integral or in fluid communication with said patient interface, said outlet means being composed substantially of a single material, and said flexible portion comprising a portion of said outlet means in which the thickness of said material is substantially less than, and therefore substantially more flexible than, the remainder of said outlet means.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a block diagram of a humidified continuous positive airway pressure (system) as might be used in conjunction with the present invention,

Figure 2 is an illustration of the nasal mask in use according to the preferred embodiment of the present invention,

Figure 3 is a side elevational view of the mouthpiece as being used by a patient,

Figure 4 is a perspective view from above of the mouthpiece,

Figure 5 is a perspective view from one side and from an inward direction of the mouthpiece of Figure 4,

Figure 6 is a cross-section of the mouthpiece of Figure 4,

Figure 7 is a cross-sectional view of the mouthpiece of Figure 4 and a user with the mouthpiece in place to demonstrate the location and positioning thereof in relation to the main features of the user's anatomy,

Figure 8 is a perspective view of the mouthpiece with the outer flap in place,

Figure 9 is a perspective view of the outer flap bent back,

Figure 10 is a cutaway view of the mouthpiece with the outer flap in use,

Figure 11 is a perspective view of the outer flap including the ventilation apertures and moisture barrier,

Figure 12 shows the outlet vent sleeve installed on the elbow,

Figure 13 shows the outlet vent sleeve in isolation,

Figure 14 shows the elbow in isolation,

Figure 15 shows the one piece elbow outlet vent interior,

Figure 16 shows the one piece elbow outlet vent exterior,

Figure 17 shows a cross section of the mouthpiece with a dispersing filter,

Figure 18 shows a perspective view of the mask with cushion,

Figure 19 is a cuttaway view of the mask showing the cushion,

Figure 20 is a cuttaway view of the periphery of the outer membrane,

Figure 21 is a cuttaway view of the periphery of the mask body portion,

Figure 22 shows a make with the forehead rest on a user, and

Figure 23 shows the forehead rest in isolation.

The present invention provides improvements in the delivery of CPAP therapy. In particular a patient interface is described which is quieter for the user to wear and reduces the side leakage as compared with the prior art. It will be appreciated that the patient interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with reference to use in a humidified CPAP system. It will also be appreciated that the present invention can be applied to any form of patient interface including, but not limited to, nasal masks, oral masks and mouthpieces.

With reference to FIG. 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as user input means or dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The

controller may also receive input from other sources, for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in FIG. 1.

Blower 15 is provided with variable pressure regulating means or variable speed fan 21 which draws air or other gases through blower inlet 17. The speed of variable speed fan 21 is controlled by electronic controller 18 (or alternatively the function of controller 18 could carried out by controller 9) in response to inputs from controller 9 and a user set predetermined required value (preset value) of pressure or fan speed via dial 19.

Nasal Mask

According to a first embodiment of the present invention the patient interface is shown in Figure 2 as a nasal mask. The mask includes a hollow body 102 with an inlet 103 connected to the inspiratory conduit 3. The mask 2 is positioned around the nose of the user 1 with the headgear 108 secured around the back of the head of the patient 1. The restraining force from the headgear 108 on the hollow body 102 and the forehead rest 106 ensures enough compressive force on the mask cushion 104, to provide an effective seal against the patient's face.

The hollow body 102 is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art.

Mask Cushion

Referring now to Figures 18 and 19 in particular, the mask cushion 1104 is provided around the periphery of the nasal mask 1102 to provide an effective seal onto the face of the user to prevent leakage. The mask cushion 1104 is shaped to approximately follow the contours of a patient's face. The mask cushion 104 will deform when pressure is applied by the headgear 1108 to adapt to the individual contours of any particular user. In particular, there is an indented section 1150 intended to fit over the bridge of the user's nose as well as a less indented section 1152 to seal around the section beneath the nose and above the upper lip.

In Figure 19 we see that the mask cushion 1104 is composed of a inner foam cushion 1110 covered by an outer sealing sheath 1112. The inner cushion 1110 is constructed of a resilient material for example polyurethane foam, to distribute the pressure evenly along the seal around the user's face. The inner cushion 1110 is located around the outer periphery 1114 of the open face 1116 of the hollow body 1102. Similarly the outer sheath 1112 may be commonly attached at its base 1113 to the periphery 1114 and loosely covers over the top of the inner cushion 1110.

In the preferred embodiment shown in Figures 19-21 the bottom of the inner cushion 1110 fits into a generally triangular cavity 1154 in the hollow body 1102. The cavity 1154 is formed from a flange 1156 running mid-way around the interior of the hollow body.

The outer sheath 1112 fits in place over the cushion 1110, holding it in place. The sheath 1112 is secured by a snap-fit to the periphery 1114 of the hollow body. In Figures 20-21 the periphery 1114 is shown including an outer bead 1158. The sheath 1112 includes a matching bead 1159, whereby once stretched around the periphery, the two beads engage to hold the sheath in place.

Forehead Rest

In the preferred embodiment of the present invention the nasal mask 2102 includes a hinged forehead rest 2106 (seen in Figures 22 and 23). The attachment of the forehead rest 2106 to the hollow body 2102 effectively allows the forehead rest 2106 to move freely in proximity to the user but with no lateral movement.

In one form shown in Figure 23, pins 2130 are provided mounted on a base 2132

attached to the hollow body 2102. These pins 2130 are co-axial within cylinders 2131 mounted on a bridge member 2136.

At the top end 2142 (around the user's forehead) of the bridge member 2136 harnessing slots 2138 are provided which allow straps from the headgear to be inserted to secure the mask to the headgear. For the user's comfort one or more resilient cushions 2140 are provided underneath the top end 2142 of the bridge member 2136, which rest on the forehead of the user. The cushion 2140 might be constructed of silicon or any foam materials as is known in the art for providing cushioning.

For example the forehead rest 2106 described previously may include a weakened section 2130 at its base 2132 which allows the joining member 2136 to pivot from the hollow body 2102. The bridge member extends up to the forehead of the user. In a further alternative the mask may include a vertical upwardly extending inlet. In this case the member 2136 is hinged at its base 2132 to either side of the inlet passage. Again the member would then extend to the forehead.

Alternatively any well-known form of hinge can be used to provide the pivoting action.

Mouthpiece

Now with reference to a further inlet embodiment of the present invention the patient interface 2 is shown in Figures 3 to 10 as a mouthpiece. In this embodiment, the mouthpiece 50 includes a vestibular shield 49 being a generally flat and generally rectangularly-shaped member in front elevation having a curved profile that reflects the curvature of a user's jaw and in turn the curvature of the labial vestibule region. A gases passageway extends through the vestibular shield from an inlet 51 to an outlet 52 in much the same way as with the earlier embodiments. In the preferred embodiment the inlet 51 is provided by a flattened oval-shaped connector 53. The outlet 52 has an even more laterally extended flattened oval shape 54. The major differences between the mouthpiece 50 and the embodiments described above are provided on the inner face of the vestibular shield. Most prominently, the mouthpiece 50 includes a tongue depressor 55 extending from the inner face of the vestibular shield 49. The operation of the tongue depressor will be described further on with reference to Figure 5. The tongue depressor includes a vertical stiffening flange 56 centrally located on its upper surface and

extending from the gases outlet 52. In use gases flow easily around the stiffening flange 56 effectively bifurcating the gases outlet 52. The tongue depressor 55 further includes a pair of vertically extending spacers 57 which in use may abut against the roof of the wearer's mouth and ensure that the tongue cannot completely block the air passageway. In the mouthpiece 50 the sealing effect of the vestibular shield 49 against the lips of the user is enhanced by providing teeth abutments of significantly increased thickness than the raised area 20 of the earlier embodiments. In particular, an upper teeth abutment 58 and a lower teeth abutment 59 are provided, with the lower teeth abutment 59 protruding further from the inner face of the vestibular shield 49 than the upper teeth abutment 58. This difference serves to match the typical over-bite of most users. The abutments 58 and 59 are not required to be wider than the gases outlet 52.

A notch 60 is provided centrally in the upper edge of the vestibular shield 49 to accommodate the upper frenal attachment. A slight bead 61 is provided around the edge of the vestibular shield 49 for user comfort, with the vestibular shield 49 otherwise being very thin for additional suppleness.

Referring particularly to Figure 6, in its preferred form the mouthpiece 50 is preferably formed by over-moulding a soft and supple material part 70 over a stiffer material part 67. These can generally be termed the shield part and the passageway-forming insert. The passageway-forming insert preferably includes a pair of upper and lower vertical flanges 63 and 64 to fully engage within the supple material. The passageway-forming insert 67 includes the vertically extending stiffening flange 56 of the tongue depressor 55, together with a curved planar portion 71 forming the backbone of the tongue depressor 55. The vertically extending spacers 57 are of the soft and supple material and are part of the over-moulding 70, as are the upper and lower teeth abutments 58 and 59.

Referring now to Figure 7, use of the mouthpiece according to Figures 4 to 6 is depicted. With the present mouthpiece 50, the upper and lower lips 85, 86 are further distended by the abutment action of the abutments 75, 76 against the upper and lower teeth 87, 88 respectively, thus forming a seal of greater pressure between the lips 85, 86 and the upper and lower portions respectively of the vestibular shield 49. A lower face

77 of the tongue depressor 55 impinges if necessary on the upper surface 72 of the tongue 85 and retains the tongue in the lower portion of the mouth. This ensures a clear gases outlet 52 from the gases passageway through the vestibular shield. The vertically extending spacers 57, if forced by pressure from the tongue, will engage against the roof of the user's mouth and maintain a clear air passageway. This stops the sleeping patient unconsciously blocking the oral passageway and reverting to nasal breathing.

Referring now to Figure 8 of the present invention is illustrated including an extra-oral sealing flap 110. The flap 110 in its natural bias is tapered, the wide open end of which is shaped to conform to the facial contours around the outside of the mouth of a user. The narrow end joins to a cylindrical section, which is designed to slide over the inlet port 114 of the mouthpiece 112. While this is one method of attachment the flap 100 might also be constructed as an integral part of the mouthpiece 112. The flap 110 needs to be constructed of flexible material, therefore materials such as silicone rubber can be employed to fashion the flap.

The outer flap 110 is seen in Figure 9, in a bent back position. It will be appreciated that when the mouthpiece 112 is being inserted into the mouth of a user, the outer flap 110 is intended to be in this bent back position to aid insertion. Prior to insertion, the outer flap is bent back by simply pressing on its outer periphery 116, until it snaps into the bent back position, in which it will stay unaided.

In Figure 10 we see the outer flap 110 in use with the mouthpiece 112 in the mouth 117 of a user 120. Once correctly positioned in the mouth 116, the outer flap 110 may be adjusted into its operational position by pressing on its outer periphery 116 until it snaps back to press against the outside of the mouth 118. Due to the relative position of the vestibular shield 122 and the outer flap 110, the outer flap 110 is unable to fully reach its natural bias and thereby inflicts a compressive force on the outside of the mouth 118.

It will be appreciated that as well as providing a substantially airtight seal the addition of the outer flap provides enough compressive force on the mouth to keep the mouthpiece and conduit in place without the need for straps. This allows the administering of CPAP therapy to be considerably less obtrusive than traditional

methods.

In a further additional improvement shown in Figure 11, the outer flap 300 is shown in perspective. Included are ventilation apertures 302, 303 either side of the gases port 304, which are surrounded by a ridge 306 acting as a moisture barrier. The apertures 302,303 are provided such that any excess moisture leaking from the mouth will migrate to the apertures where they may evaporate. Small vents in the conduit may be used to direct small amounts of pressurised gas at the apertures to aid evaporation. The ridge 306 is included to ensure that no moisture migrates further into the sealing region 308, as this would be detrimental to the sealing properties of the flap.

Interface Connection

Attention is now directed to Figure 3. It has been found that an additional factor in the effectiveness of any patient interface 2, is the manner in which the interface is connected to the breathing circuit 41. The weight of the breathing circuit 41, and any attempted movement of one other of the breathing circuit 41 and the interface 2 relative to the other, is one of the largest influences tending to dislodge the interface 2. It must be noted that the interface 2 must remain in position and maintain a seal during all sleep, when the user has no muscle tone.

The connection 40 as provided in the present invention between the breathing circuit 41 and the interface 2 decouples the interface 2 from the breathing circuit 41. As a result, the connection 40 is effective in reducing the forces placed on the interface 2 by the breathing circuit 41 when the user moves around during sleep. In the preferred sleeping position, the breathing circuit 41 is laid across the chest 43 of the user, and may be secured to the user's bed clothes or sleeping garments. The breathing circuit 41 is preferably laid on the chest of the user to take the weight of the breathing circuit 41 off of the interface 2.

To connect between the gases outlet 14 which is vertical when the user is laying on his or her back and the breathing circuit 41 which is generally horizontal, an L-shaped elbow 45 is incorporated in the connection 40. The elbow 45 may be incorporated in the interface 2. The elbow 45 is formed at a right angle and provides a positive pressure on the interface 2. The elbow 45 may include a swivel joint and may

be disconnected from gaseous outlet 42. The connection 40 further includes an extremely flexible connecting tube 46 provided between the elbow 45 and the breathing circuit 41. The connecting tube 46 is preferably connected to the breathing circuit 41 by a swivel joint 48 for reasons described herein. The breathing circuit 41, while flexible, will necessarily be stiff enough to maintain its integrity over comparatively long tuns, while the connecting tube 46, being only a short length, for example 10 centimetres, merely has to span between the user's mouth and chest, and can thereby be made in a manner that would not be suitable for long runs. Furthermore, as a result of the short length of the connecting tube 46, the connecting tube 46 does not need to incorporate significant insulation or heating capability. The connecting tube 46 may be formed from a thin plastic membrane supported over a helical or double helical or corrugated supporting ribs. In such a case, the support makes the connection tube 46 laterally flexible and resistant to torsion. The elbow swivel joint 45 allows for movement of the connection tube 46 relative to the interface 2. The swivel joint 48 allows for movement of the connection tube 46 relative to the breathing circuit 41. It is to be understood that one or both of the swivel joints 45, 48 could be eliminated, but the preferred embodiment includes swivel joint 48.

Outlet Vent

The present invention will now be described with reference to the various different embodiments previously described. In order to reduce the noise caused by expiratory gases being expelled from the patient interface 2, the present invention is illustrated in Figures 12 to 17 with the elbow connector (previously designated as 45) including an outlet vent. It would be appreciated by one skilled in the art that the elbow connector as described herein will be equally applicable to all proceeding embodiments and all other forms of patient interface for delivering CPAP therapy.

Referring particularly now to Figures 12 to 14, the elbow connector is illustrated including a flexible sleeve 400 which fits overtop of the elbow connector. The sleeve 400 is preferably constructed of silicon, but it will be appreciated by one skilled in the art that a number of other flexible materials will be equally applicable. The sleeve 400 includes locating indents 402 which once installed on the elbow connector match up

with and lock into locating notches 404 on the elbow connector. The location is necessary so that the outlet aperture 406 in the elbow connector always matches up with the outlet vents 408 in the outlet sleeve 400. This then prevents the undesirable situation where the sleeve could slip and the outlet vents 408 not match up with the outlet aperture 406 with resulting consequences to the patient.

Referring now to Figures 15 and 16, the present invention is shown with a one-piece elbow. In this case the elbow is preferably constructed of either "Hytrel" plastic or polycarbonate. In this fashion the elbow connector is manufactured to have a thin portion 410 surrounding the outlet vents 412 in comparison to the remainder of the elbow connector which is considerably thicker. The properties of the material chosen for the elbow connector are such that its flexibility is dependent on its thickness. Therefore in the thin section 410 the elbow connector is relatively flexible and in the remainder is relatively rigid. Accordingly the outlet vents 412, which are also rounded on their periphery are formed in a flexible portion, and therefore achieve the desirable low noise properties when expiratory gases are vented therethrough.

Flow Diffuser

Referring now particularly to the use of mouthpieces, a further improvement is shown in Figure 17. It is documented that when CPAP therapy is delivered to patients they often complain of drying of the airways and resulting irritation and discomfort. In particular when a concentrated airflow of under humidified gases flows past the oral or nasal cavities, or the airway of the user then drying and irritation may occur. Accordingly the present invention as illustrated in Figure 17 includes a mouthpiece with a flow diffuser 500.

As described in the preceding embodiments, the mouthpiece sits with a vestibular shield 502 between the gums 504 and the lips 506 of a user. An outer flap 508 provides compressor force on the lips 506 to keep the mouthpiece in place in the user's mouth. Again the mouthpiece includes a tough depressor 510 extending into the user's oral cavity.

In the preceding embodiments the delivered gases would flow through passageway 512 in the mouthpiece, causing a relatively concentrated flow of gases to

flow through the oral cavity and down the airway. With the flow diffuser 500 fitted overtop of the passageway 512 the flow is defused over the much larger area of the diffuser 500, and therefore both the speed and side effects are reduced.

Alternatively the space between the passageway 512 and the diffuser 500 could be filled with a Humidity Moisture Exchange (HME) material. This would allow moisture through on the inspiratory flow put prevent it passing out an expiration. This would further prevent against the patient's passageways drying out. Further, if the HME material was in the form of foam, then it might also act as the diffuser 500. It will also be appreciated that the HME material could be used in the space 516 all the way out to the elbow connector (not shown) to maximise its effect.

It will be appreciated that by providing such a system the present invention effectively minimises the noise generated by the outward flow of expiratory gases from the mask. The present invention requires little or no maintenance. The present invention also provides a flow diffuser for use with the mouthpiece, which reduces any side effects of orally delivered CPAP therapy and improves user comfort.

CLAIMS

1. A device for delivering a supply of gases to a user comprising:

a patient interface, in use in fluid communication with said supply of gases, engaging with said user and thereby supplying said gases to said user.

outlet means associated with said patient interface including a plurality of outlet vents formed in a flexible portion of said outlet means, said outlet means in use passing a substantial portion of the expired gases of said user.

2. A device for delivering a supply of gases to a user as claimed in claim 1 wherein said patient interface is a mouthpiece.

3. A device for delivering a supply of gases to a user as claimed in claim 1 wherein said patient interface is a nasal mask.

4. A device for delivering a supply of gases to a user as claimed in claim 2 wherein said mouthpiece comprises:

a vestibular shield having an inner surface and an outer surface, said vestibular shield having a predetermined height which will overlap said user's teeth and gums when positioned in the mouth vestibule of said user;

gases passageway means extending from said outer surface of said vestibular shield to said inner surface of said vestibular shield for allowing the passage of said gases through said mouthpiece; and

extra-oral sealing means associated with said gases passageway which may be adjusted into one of two configurations, a first condition when said mouthpiece is inserted into said user's mouth being substantially unengaged with said user's face, and a second condition when correctly positioned in said user's mouth being substantially engaged with said user's face and under compression thereupon.

5. A device for delivering a supply of gases to a user as claimed in claim 3 wherein said nasal mask comprises restraining means attached to or around the head of said user, a hard body portion having an inlet receiving said supply of gases and an open section, sealing means attached to said body portion substantially contoured to the facial contours of said user and a receiving means attached to said hard body which in use engages with

said restraining means.

6. A device for delivering a supply of gases to a user as claimed in any one of claims 1 to 5 wherein said flexible portion of said outlet means comprises a sleeve having a plurality of outlet vents, said sleeve attaching over said outlet means.

7. A device for delivering a supply of gases to a user as claimed in claim 6 wherein said sleeve composed of a substantially flexible material, said outlet means having a outlet aperture and in use said sleeve located on said outlet means such that said outlet aperture matches up with said plurality of outlet vents thereby in use passing a substantial portion of the expired gases of said user.

8. A device for delivering a supply of gases to a user as claimed in any one of claims 1 to 5 wherein said outlet means is either integral or in fluid communication with said patient interface, said outlet means being composed substantially of a single material.

9. A device for delivering a supply of gases to a user as claimed in claim 8 wherein said flexible portion comprising a portion of said outlet means in which the thickness of said material is substantially less than, and therefore substantially more flexible than, the remainder of said outlet means, and said vents located in said thin portion.

10. A device for delivering a supply of gases to a user comprising:

a nasal mask, in use in fluid communication with said supply of gases,

a first engagement means engaging said nasal mask and adapted to in use attach to the head of a user and

a second engagement means pivotally engaged to said nasal mask and adapted to in use attach to the head of a user.

11. A device for delivering a supply of gases to a user as claimed in claim 10 wherein said second engagement comprises a bridge member with a proximal end pivotably engaged to said nasal mask and a distal end; and a deformable resilient member engaged with said distal end adapted to in use provide a comfortable rest on the forehead of said user.

12. A device for delivering a supply of gases to a user as claimed in claim 11 wherein said pivoting engagement allows movement of said bridge member relative to said nasal mask on a horizontal axis, said axis in use substantially parallel to the from of the head

of a user.

13. A device for delivering a supply of gases to a user as claimed in claim 12 wherein said horizontal axis of movement allows accommodation of users with movement different sized noses.

14. A device for delivering a supply of gases to a user comprising:

a hollow body including a gases inlet and gases delivery aperture, said gases inlet in use in fluid communication with said supply of gases,

a first resilient sealing means engaged around the periphery of said gases delivery aperture, and

a second flexible sealing means engaged around or adjacent to the periphery of said gases delivery aperture, and at least partially covering said first resilient sealing means,

wherein said first resilient sealing means and said second flexible sealing means being shaped to approximate the facial contours of a user.

15. A device for delivering a supply of gases to a user as claimed in claim 14 wherein said first resilient sealing means is able to deform substantially independently of said second flexible sealing means.

16. A device for delivering a supply of gases to a user as claimed in claims 14 or 15 wherein said first resilient sealing means is a deformable cushion.

17. A device for delivering a supply of gases to a user as claimed in claim 16 wherein said second flexible sealing means is a sheath substantially covering, and substantially thinner than, said cushion.

18. A device for delivering a supply of gases to a user as claimed in any one of claims 14 to 17 wherein said hollow body having a flange at least partially around the interior of said hollow body, said flange and said interior forming a cavity adapted to house in use a part of said first resilient sealing means.

19. A device for delivering a supply of gases to a user as claimed in claim 18 wherein the periphery of said gases delivery aperture having engagement means and said second resilient sealing means having matching engaging means, whereby in use said second resilient sealing means is adapted to fit at least partially over the periphery of

said hollow body said engaging means and said matching engaging means thereby in use holding said second resilient sealing means substantially in position to seal against the facial contours of a use.

20. A system capable of being used for nasal delivery of gases pressurized above ambient to a user comprising or including a mask, a breathing tube; and decoupling means for connecting said mask to said breathing tube, said decoupling means comprising a connection tube being formed of a material which is more flexible than the material of which said breathing tube is formed.

21. A device for delivering a supply of gases to a user as claimed in claim 20 wherein said connection tube is shorter in length than said breathing tube.

22. A device for delivering a supply of gases to a user as claimed in claims 20 or 21 wherein said connection tube is formed from a thin plastic membrane supported over one or more helical supporting ribs.

23. A device for delivering a supply of gases to a user as claimed in claims 20 or 21 wherein said connection tube is formed from a thin plastic membrane supported over one or more corrugated supporting ribs.

24. A device for delivering a supply of gases to a user as claimed in claims 22 or 23 wherein said ribs are formed of foamed insulating plastics.

25. A device for delivering a supply of gases to a user as claimed in any one of claims 20 to 24 wherein said decoupling means further includes a swivel joint between said connection tube and said breathing tube.

26. A device for delivering a supply of gases to a user as claimed in any one of claims 20 to 24 wherein said decoupling means further includes an L-shaped elbow connected between said mask and said connection tube.

27. A device for delivering a supply of gases to a user as claimed in claim 26 wherein said L-shaped elbow includes a swivel joint.

28. A mouthpiece for delivering a supply of gases to a user comprising:

engagement means adapted to in use juxtapose said mouthpiece in or about the oral cavity of a use and substantially seal thereabouts,

flow path means adapted to in use allow said supply of gases to be delivered to

the oral cavity of a user, wherein said gases being supplied thereto in a substantially diffused manner.

29. A mouthpiece for delivering a supply of gases to a user as claimed in claim 28 wherein said flow path means includes an inlet, in use fluid communication with said supply of gases, and an outlet in fluid communication with said outlet, wherein said outlet including a diffusing member is use through which said gases pass and are thereby discharged in a diffused manner.

30. A mouthpiece for delivering a supply of gases to a user as claimed in claim 29 wherein said diffusing member comprises a portion of porous material in use through which said gases pass.

31. A mouthpiece for delivering a supply of gases to a user as claimed in claim 30 wherein said porous material is material chosen from those known to have heat and moisture exchanging properties.

32. A nasal mask for delivering respiratory gases substantially as herein described with reference to and as illustrated by the accompanying drawings.

33. A mouthpiece for delivering respiratory gases substantially as herein described with reference to and as illustrated by the accompanying drawings.

34. A mask cushion for a respiratory nasal mask substantially as herein described with reference to and as illustrated by the accompanying drawings.

35. An outlet vent for a patient interface for delivering respiratory gases substantially as herein described with reference to and as illustrated by the accompanying drawings.

36. A forehead rest for a patient interface for delivery respiratory gases substantially as herein described with reference to and as illustrated by the accompanying drawings.

37. A CPAP system substantially as herein described with reference to and as illustrated by the accompanying drawings.

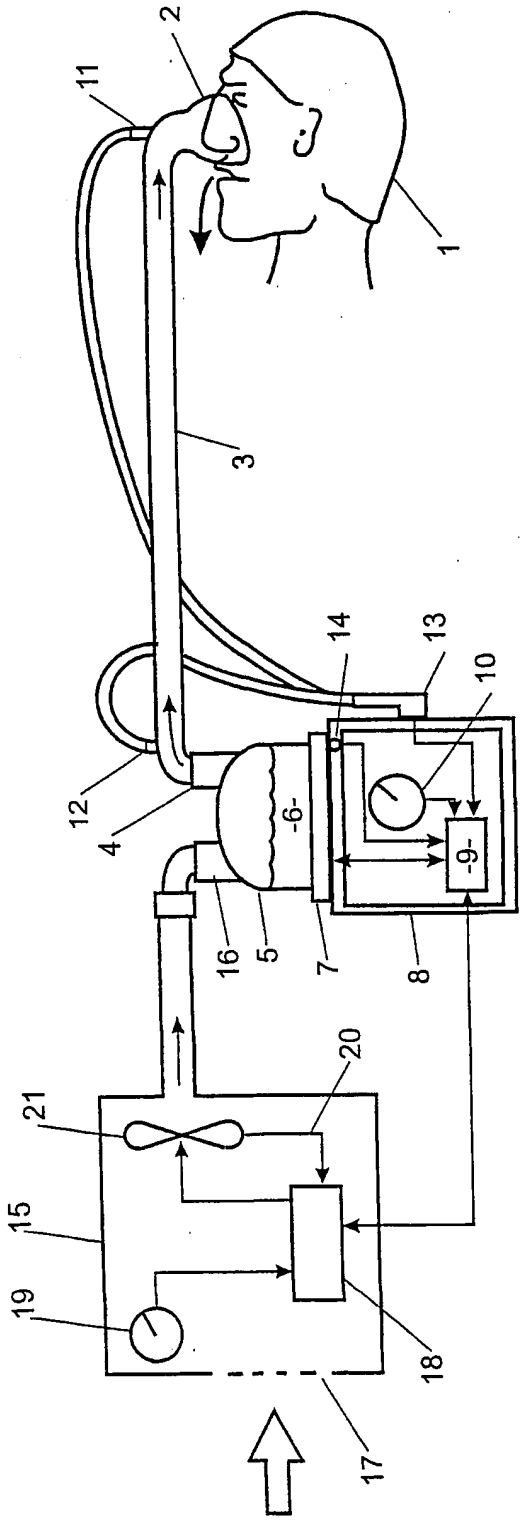


FIGURE 1

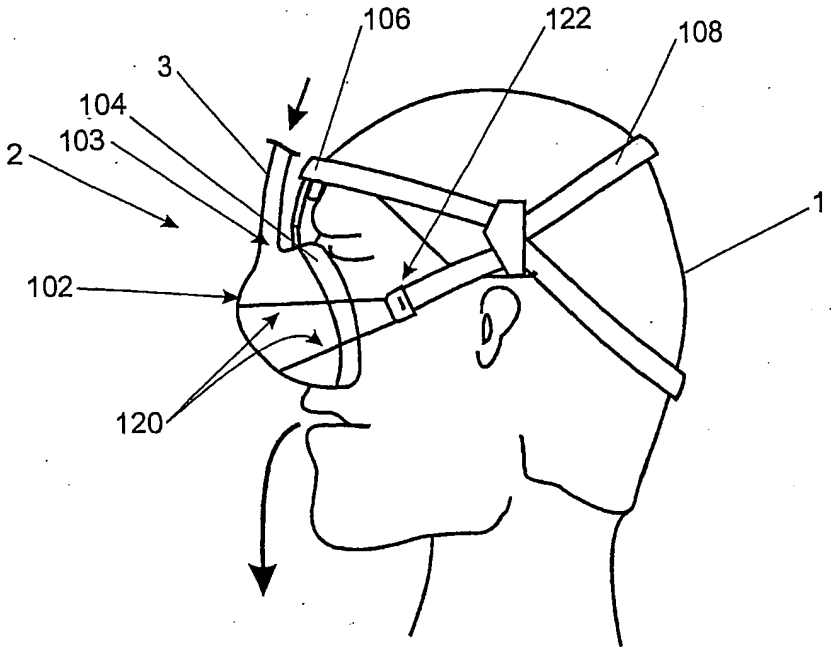


FIGURE 2

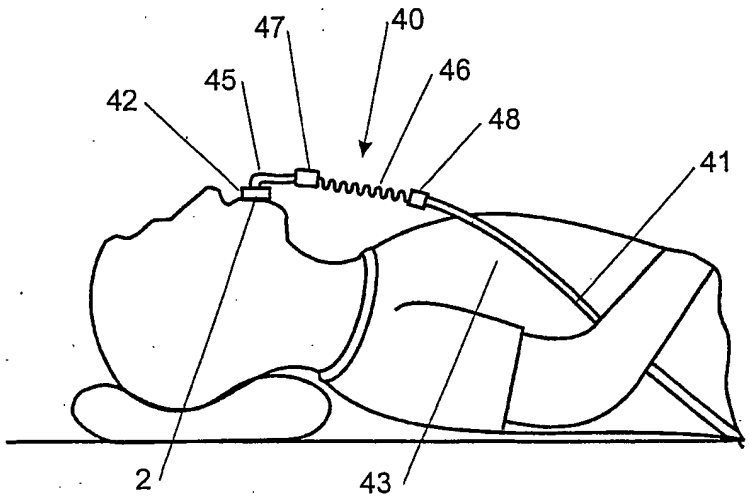


FIGURE 3

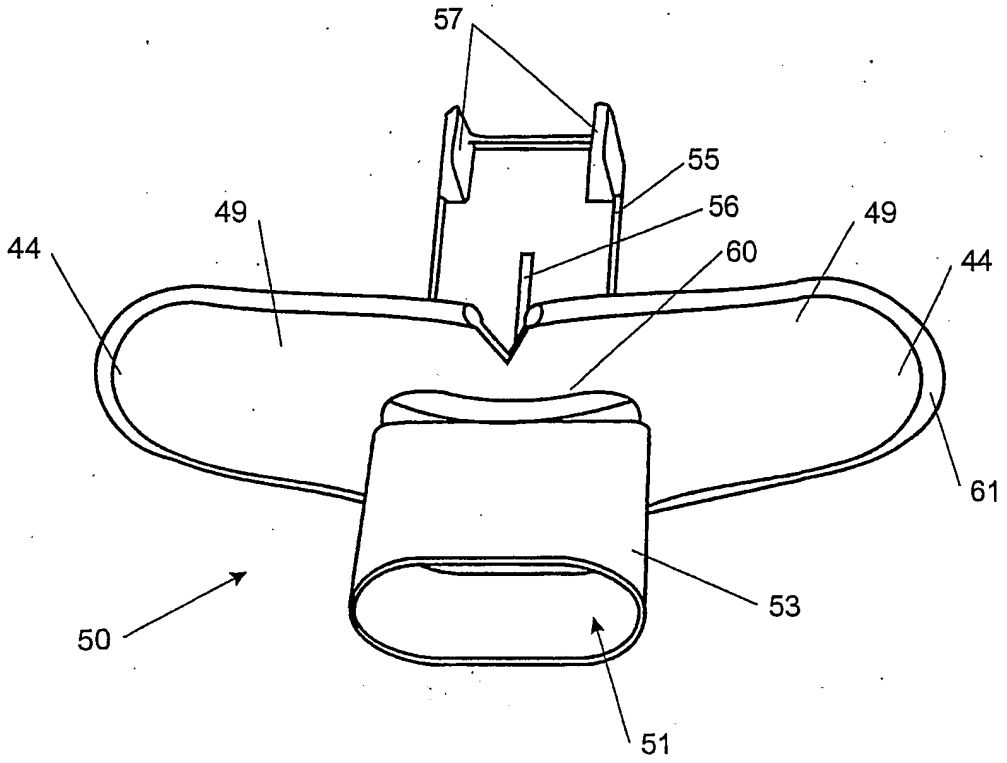


FIGURE 4

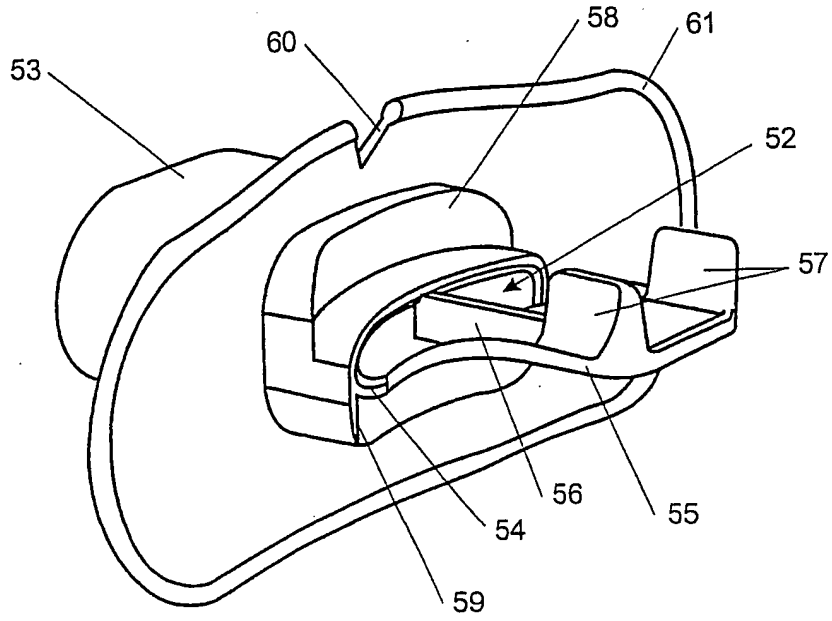


FIGURE 5

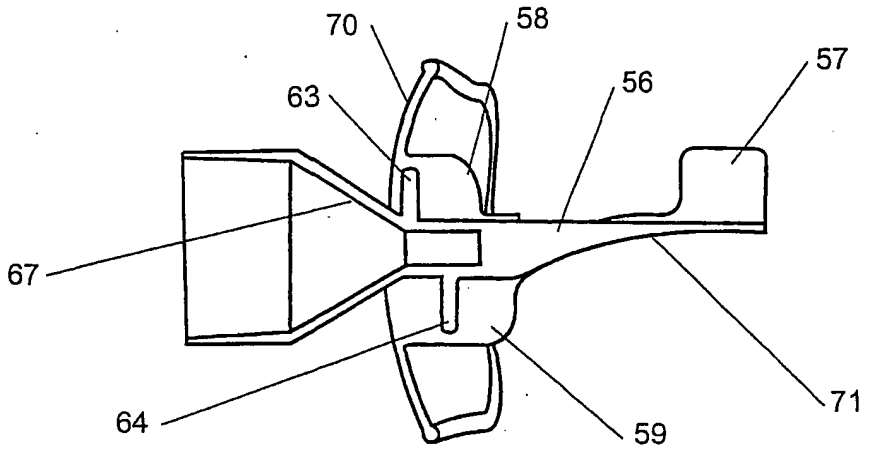


FIGURE 6

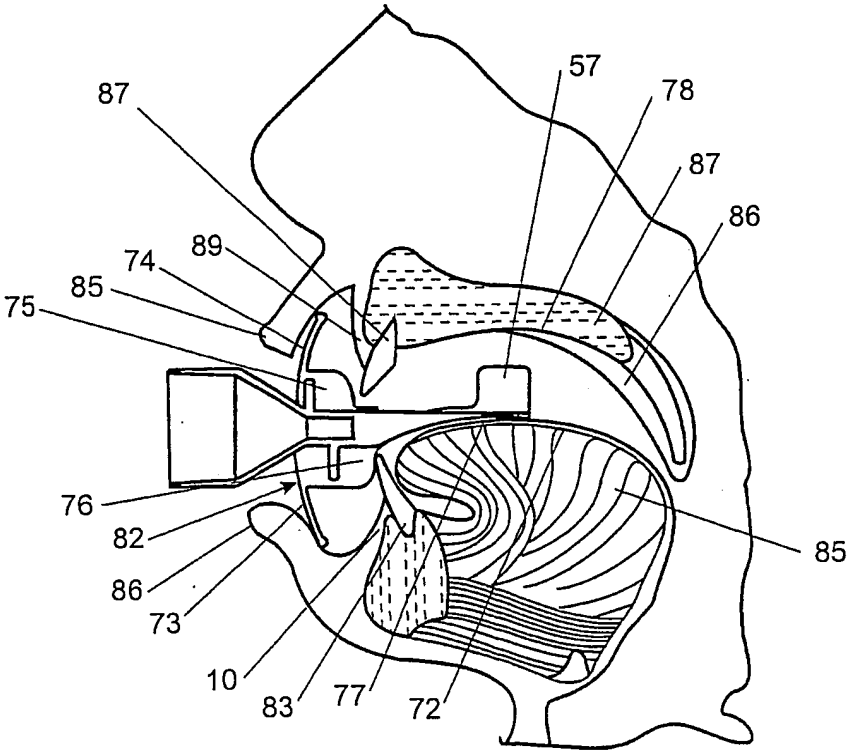


FIGURE 7

FIGURE 8

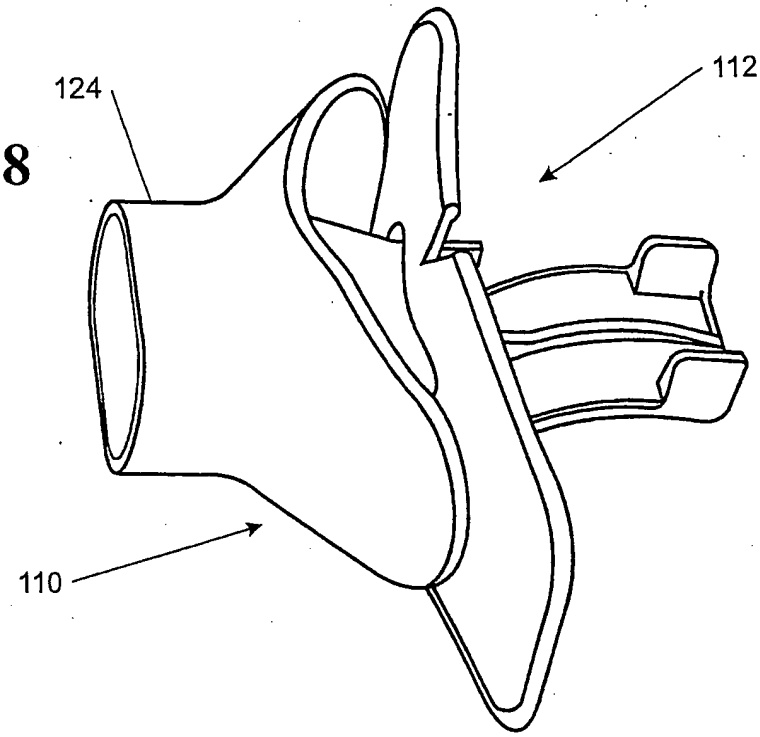
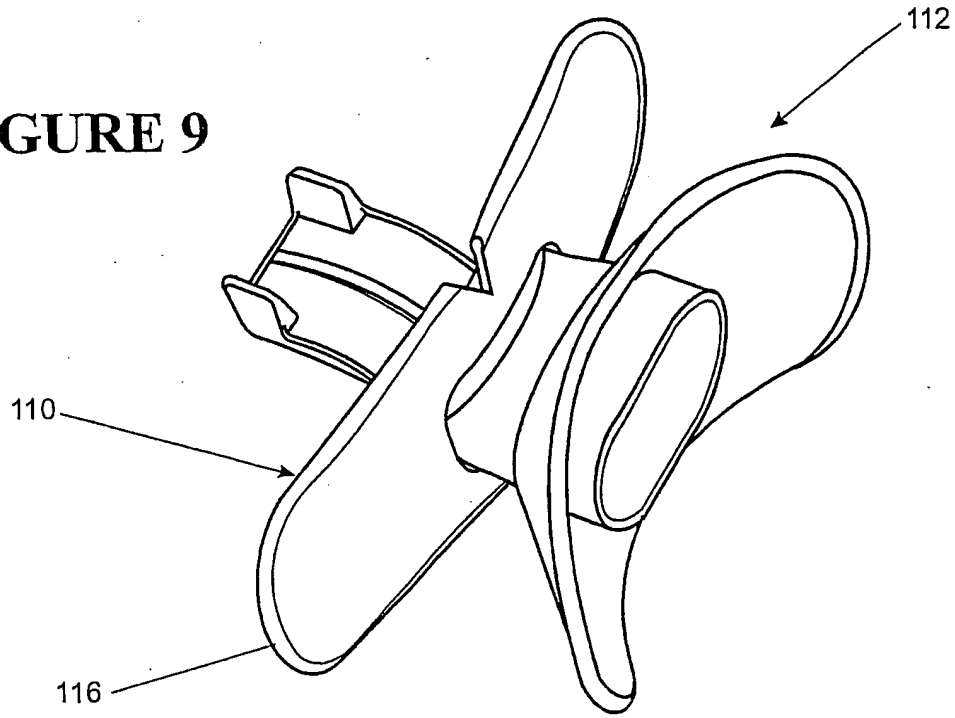


FIGURE 9



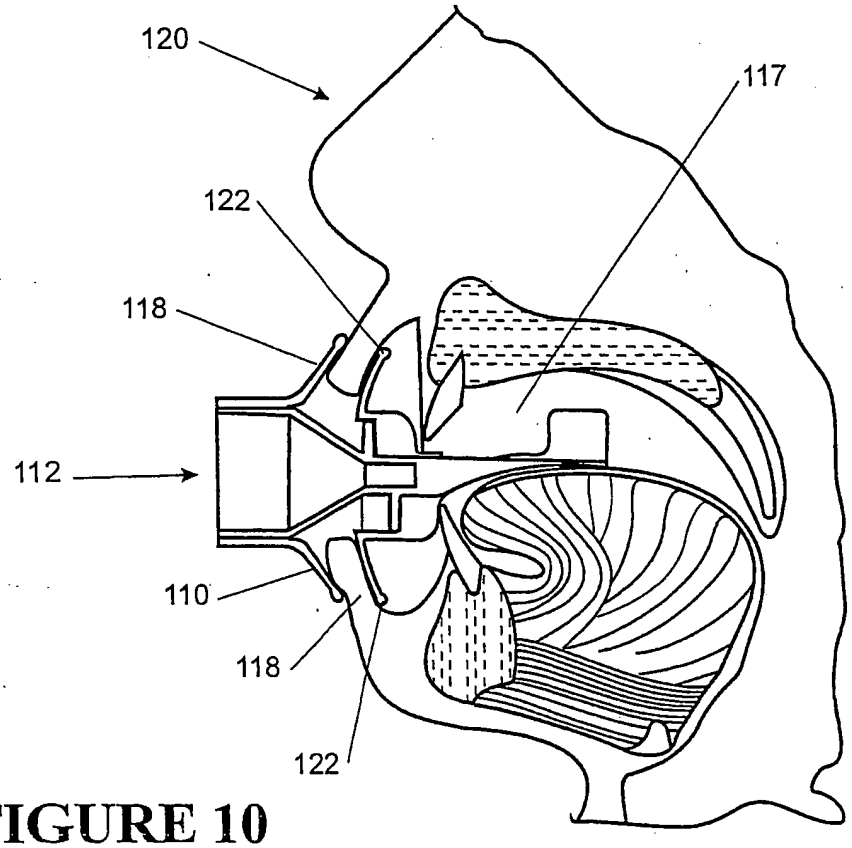


FIGURE 10

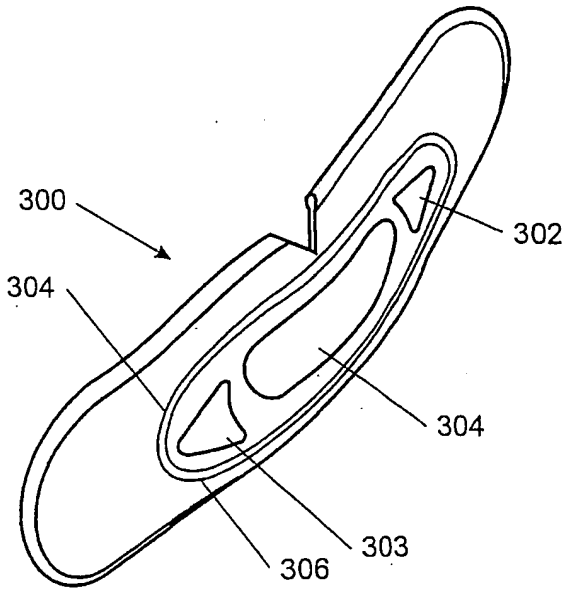


FIGURE 11

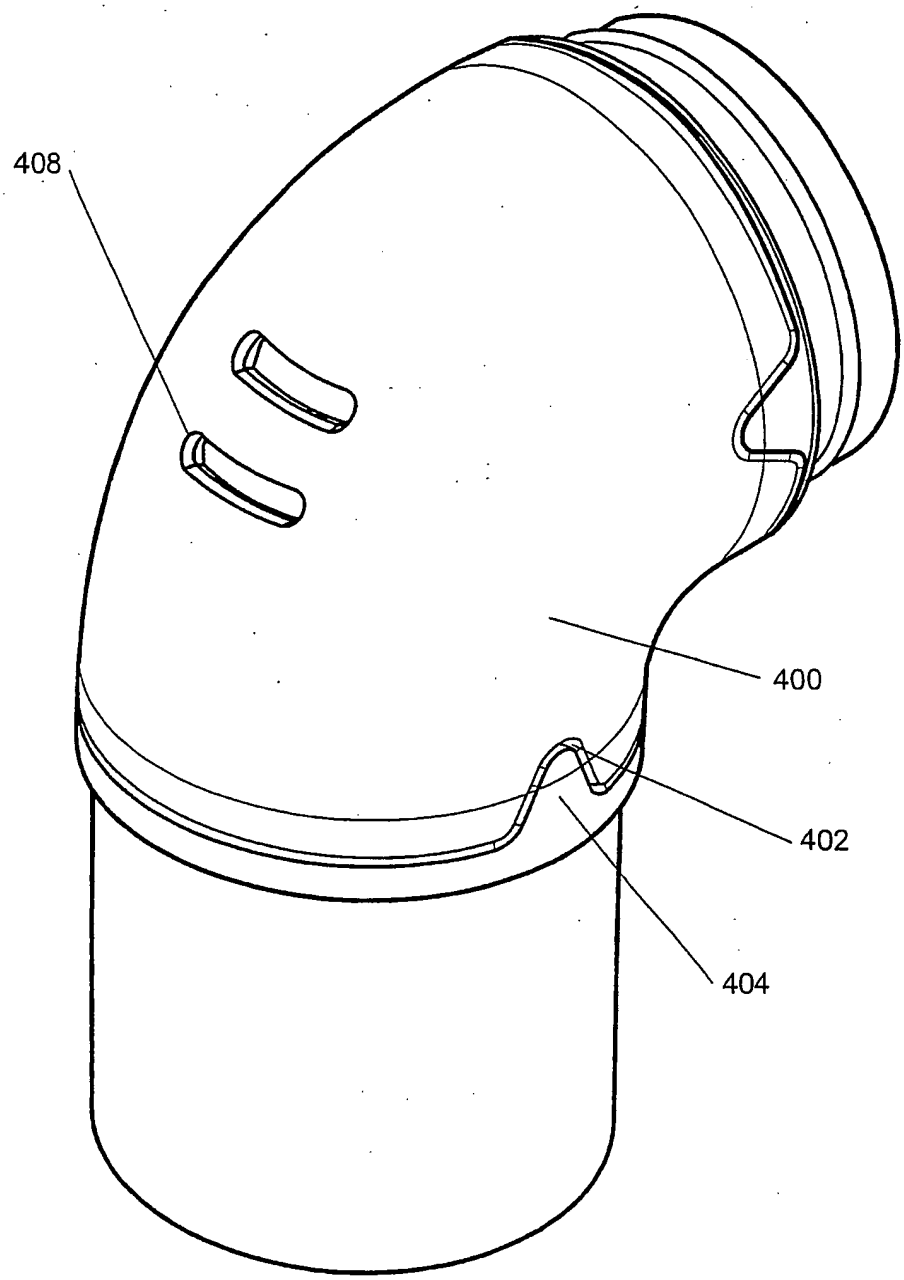


FIGURE 12

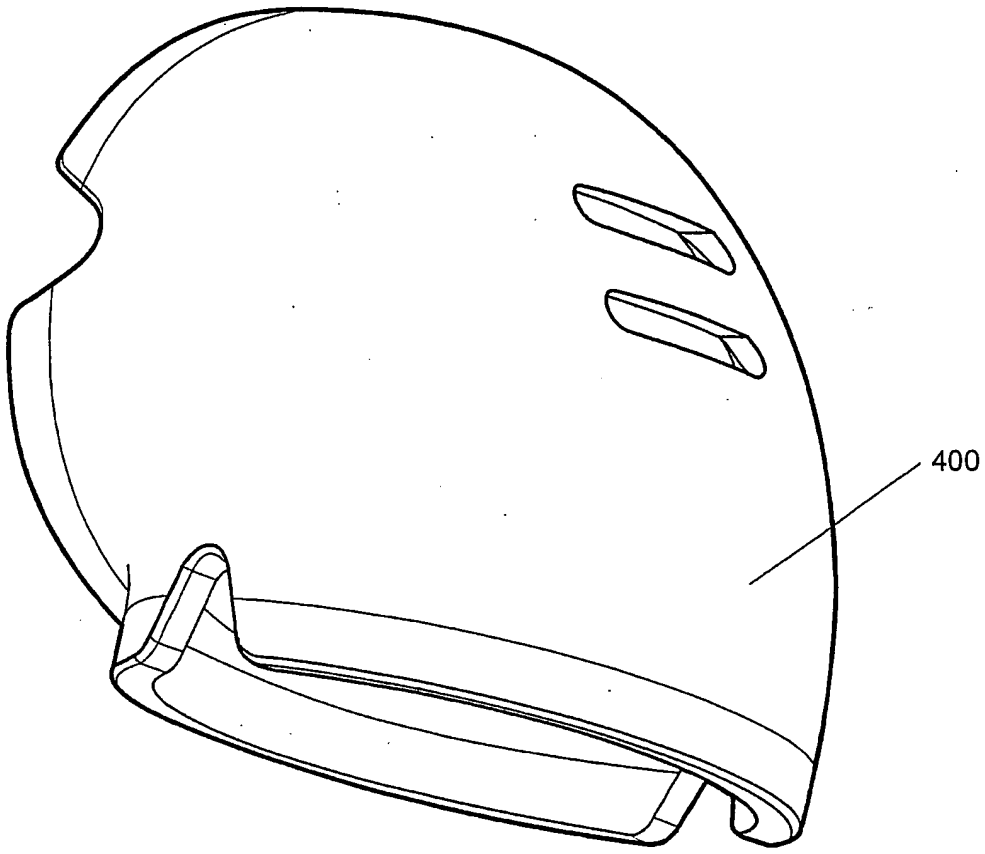


FIGURE 13

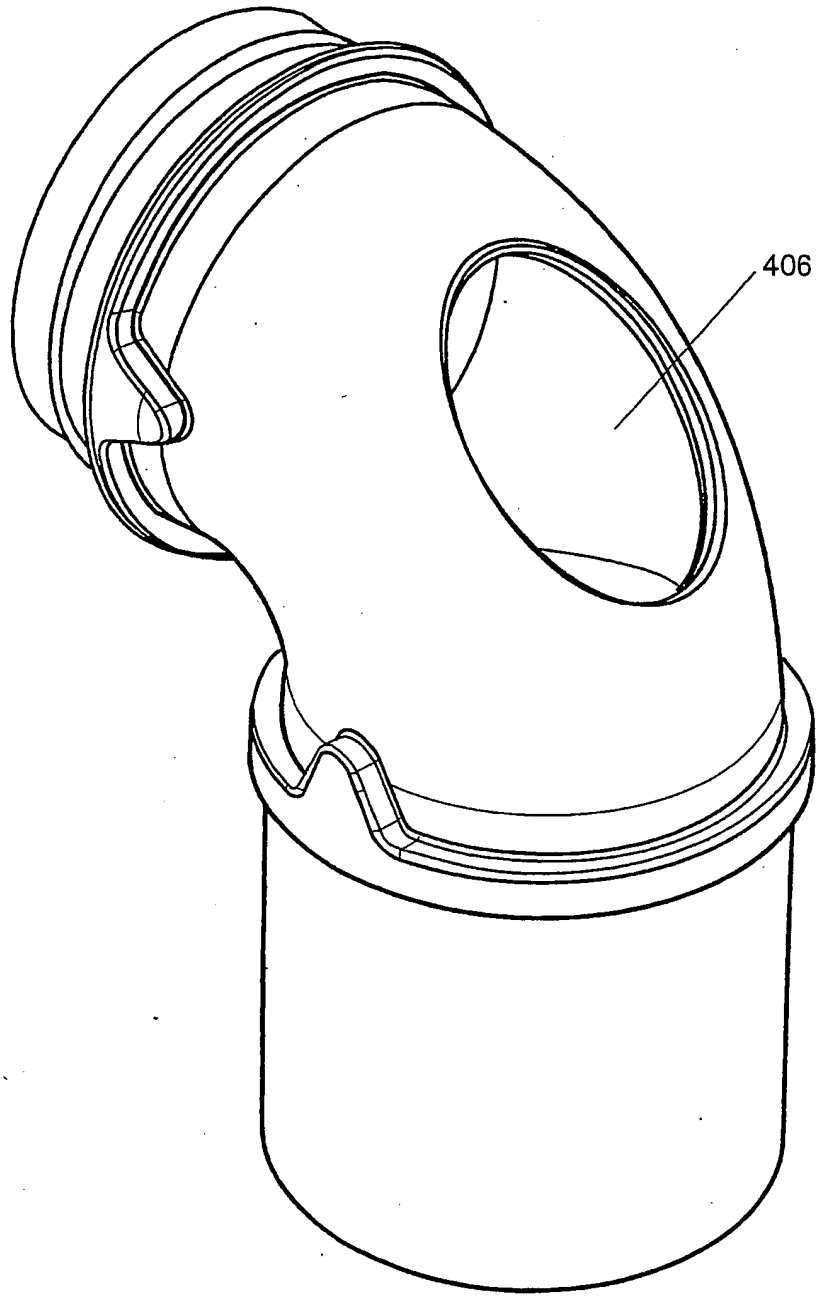


FIGURE 14

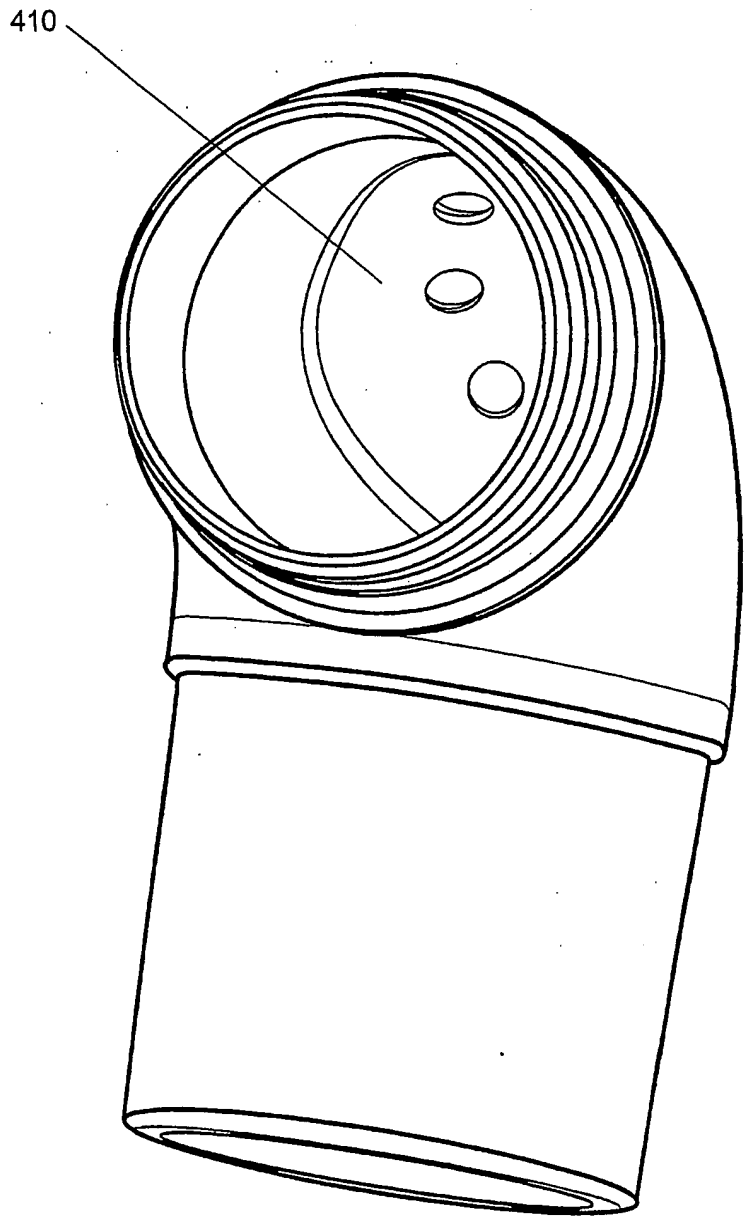


FIGURE 15

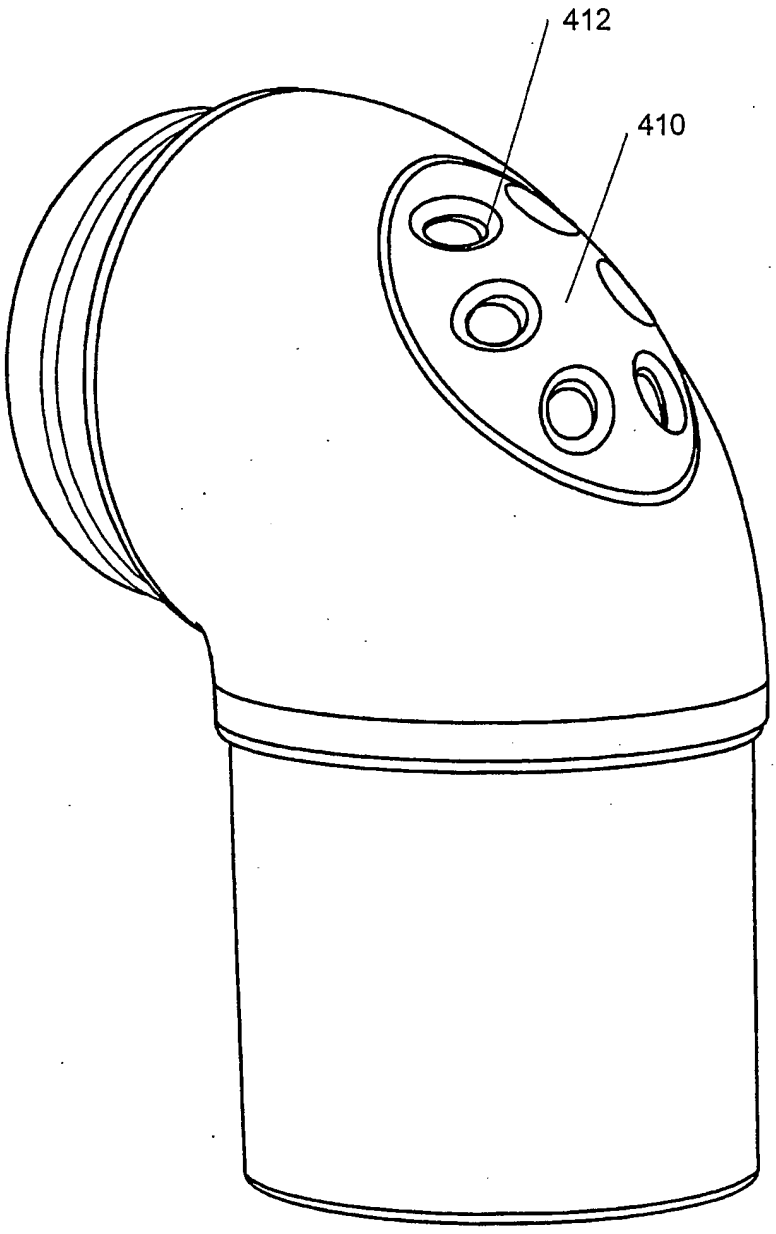


FIGURE 16

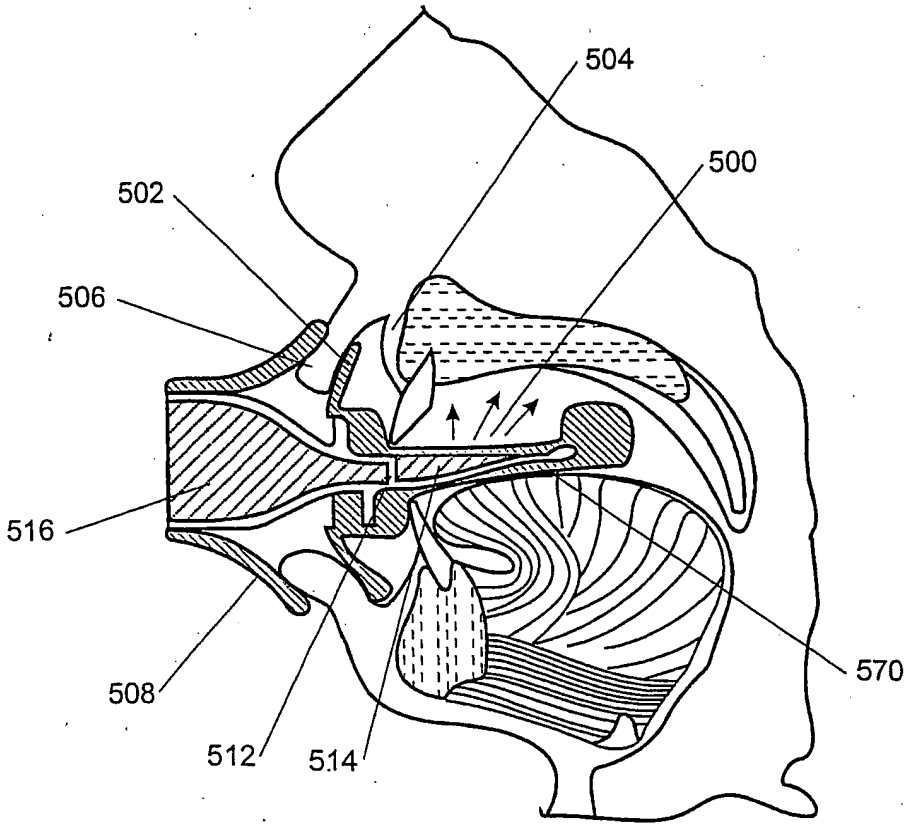


FIGURE 17

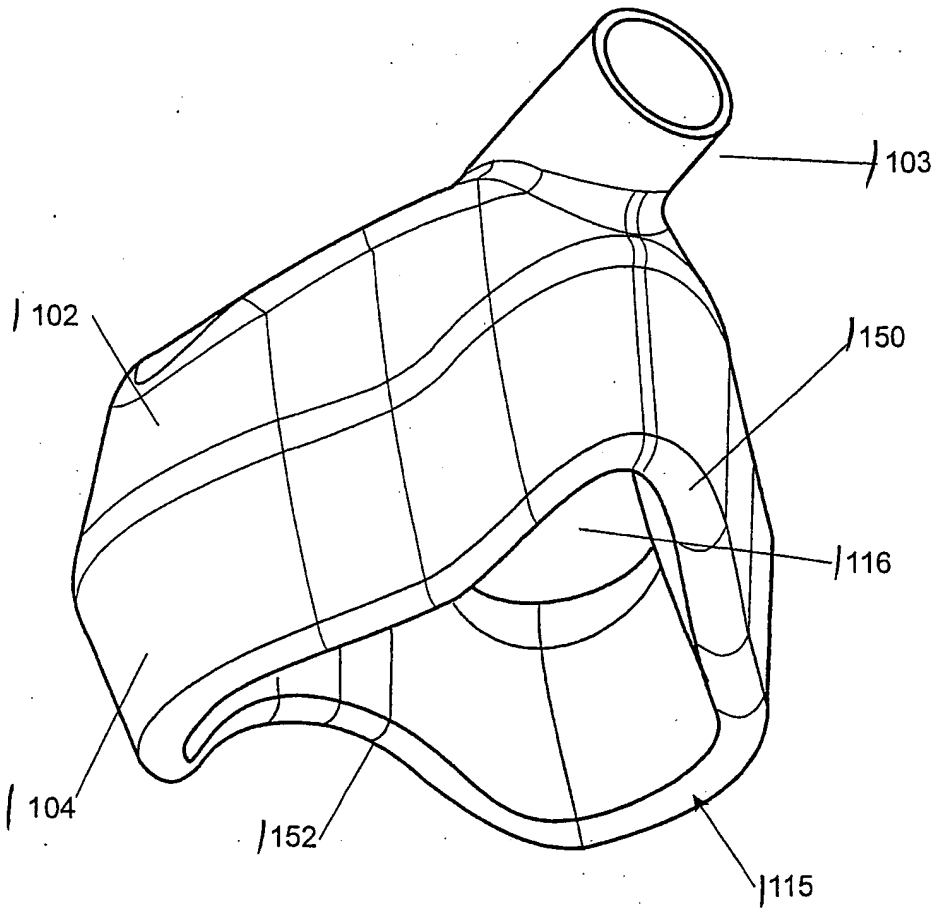


FIGURE 18

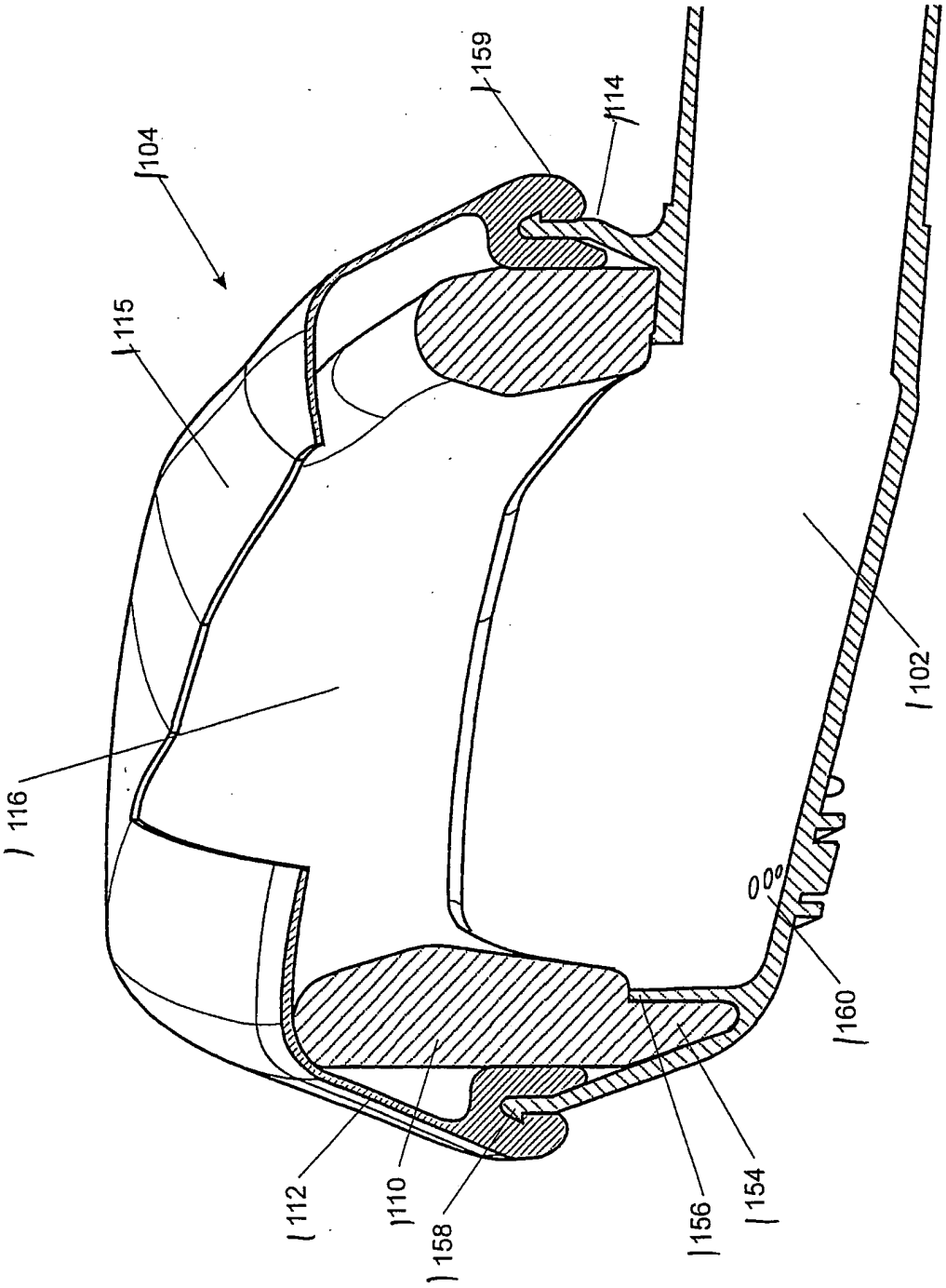


FIGURE 19

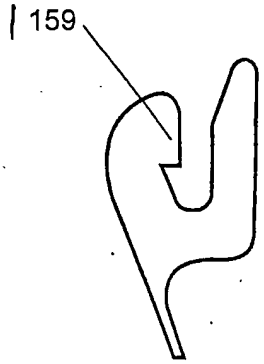


FIGURE 20

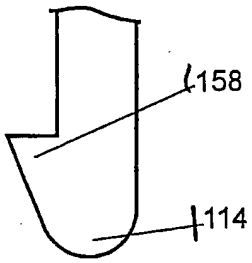


FIGURE 21

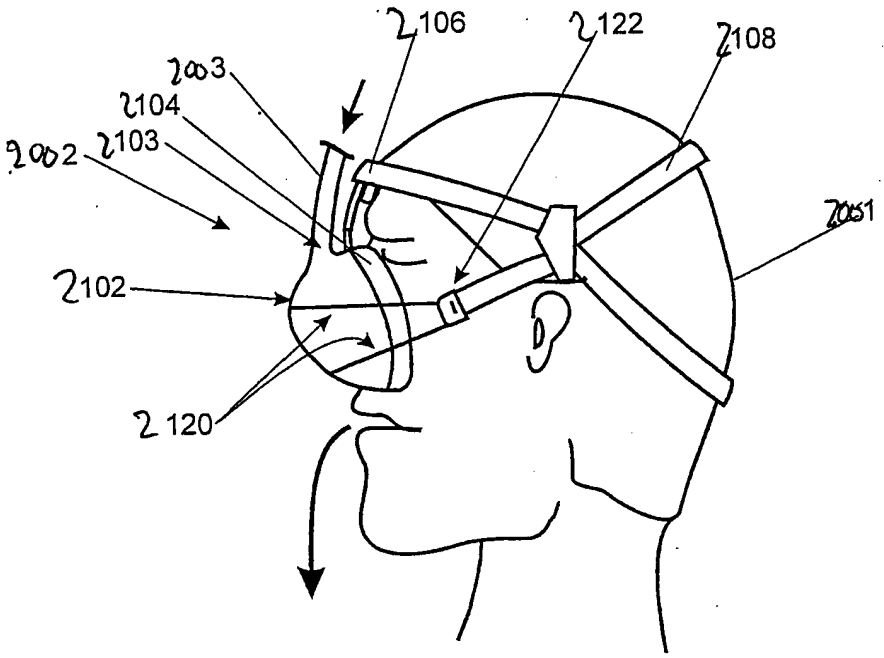


FIGURE 22

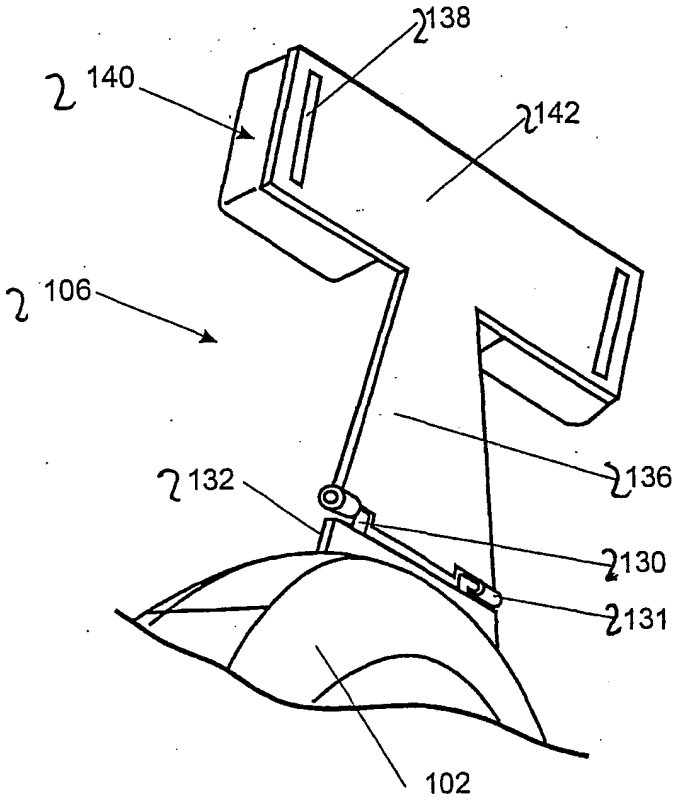


FIGURE 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ01/00110

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/00, 16/08, 39/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Refer electronic databases consulted below

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI & keywords: mask cpap respiration ventilate aperture hole flexible rubber quiet noise sound seal cushion foam cover dual twin mouth supply deliver flow porous disperse nasal nose hinge pivot turn and similar words

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/34665 A1 (RESMED LTD) 13 August 1998 whole document	1-8
P,X	WO 01/26722 A1 (MALLINCKRODT INC) 19 April 2001 page 3 lines 3-14, figure 2	1,3,5,6,8,9
X	GB 1395391 A (VICKERS LIMITED) 29 May 1975 page 1 lines 41-53, page 2 lines 47-53, figure 2	1,3,5,8

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 September 2001	21 SEPTEMBER 2001
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer A.R. HENDRICKSON Telephone No: (02) 6283 2415

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ01/00110

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CA 1039144 A (C R BARD INC) 26 September 1978 page 6 line 1 - page 7 line 4, figure 1	1,3,5,8
P,X	WO 00/78384 A1 (RESMED LIMITED) 28 December 2000 see whole document	10-13
P,X	WO 00/57942 A1 (RESMED LIMITED) 5 October 2000 see whole document	10-13
X	JP 11-000397 A (TEIJIN LTD) 6 January 1999 see figures	10-13
X	WO 98/04310 A1 (RESMED LIMITED) 5 February 1998 see page 2 line 11 - page 3 line 3 page 6 lines 4-10	14-19
X	US 5243971 A (SULLIVAN et al) 14 September 1993 see whole document	14-19
P,X	WO 00/74758 A1 (SLEEPNET CORPORATION) 14 December 2000 see pages 7-9	14-19
X	US 3747598 A (COWANS) 24 July 1973 see whole document	28-31
X	US 4201206 A (KUEHN et al) 6 May 1980 see whole document	28-31
X	WO 85/03880 A1 (LINDHOLM) 12 September 1985 see abstract, figure 1	28
A	US 5438981 A (STARR et al) 8 August 1995	28-31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ01/00110

Box I **Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

see attached sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: 1-19, 28-37

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ01/00110

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-9 are directed to a gas supply device with a plurality of vents formed in a flexible portion of an outlet means. It is considered that a gas supply device with a plurality of vents formed in a flexible portion of an outlet means comprises a first "special technical feature".

2. Claims 10-13 are directed to a nasal mask with an engagement means to attach the mask and a second engagement means to pivotally attach the mask to the head of the user. It is considered that the nasal mask with an engagement means to attach the mask and a second engagement means to pivotally attach the mask to the head of the user comprises a second "special technical feature".

3. Claims 14-19 are directed to a gas supply device with two flexible sealing means wherein each sealing means is shaped to the facial contours of the user. It is considered that a gas supply device with two flexible sealing means wherein each sealing means is shaped to the facial contours of the user comprises a third "special technical feature".

4. Claims 20-27 are directed to a system for nasal delivery of gases with a decoupling means which has a connection tube which is more flexible than the breathing tube. It is considered that a system for nasal delivery of gases with a decoupling means which has a connection tube which is more flexible than the breathing tube comprises a fourth "special technical feature".

5. Claims 28-31 are directed to a mouthpiece wherein the gases supplied to the oral cavity are supplied thereto in a diffused manner. It is considered that a mouthpiece wherein the gases supplied to the oral cavity are supplied thereto in a diffused manner comprises a fifth "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/NZ01/00110

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	98/34665	AU	53019/98	AU	58476/98	EP	968022
WO	2001/26722	NONE					
GB	1395391	NONE					
CA	1039144	NONE					
WO	2000/78384	AU	2000/16355	AU	2000/26505	AU	2000/52005
		AU	2000/52007	WO	2000/78382	WO	2000/78383
WO	2000/57942	AU	2000/34087	AU	2000/22651		
JP	11-000397	NONE					
WO	98/04310	AU	12454/97	AU	34293/97	EP	956069
		US	6112746	AU	42476/99		
US	5243971	AU	77110/91	EP	462701		
WO	2000/74758	AU	2000/51653	EP	1057494		
US	4201206	NONE					
WO	85/03880	CA	1255993	EP	174336	SE	8401143
US	5438981	US	5647355				

END OF ANNEX